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EXAMINER	
HURST, JONATHAN M	

ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/570,488	WADA ET AL.	
	Examiner	Art Unit	
	JONATHAN M. HURST	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *03/03/2006*.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 March 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/03/2006, 11/13/2006, and 12/13/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the diluent solution inlet recited in claim 12 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 12 recites a diluent solution inlet formed at a position in the middle of the solution. It is unclear how a diluent solution inlet can be formed in the middle of a solution which is flowing throughout a device. For the purposes of examination in the middle of the solution is interpreted to mean a position where the solution is circulating in the device.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 12, 14, and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by DiLeao et al. (US 4,728,430)

Regarding claim 12 DiLeo discloses a liquid flow channel for preparing a solution having a changed composition of biological components; comprising a module containing a separation membrane disposed therein and having a raw liquid inlet and a raw liquid outlet joined to a raw liquid side flow path of the separation membrane; a solution circulation channel communicating the raw liquid inlet and the raw liquid outlet and having a pump and an inlet for an object solution for separation in the middle; and a diluent solution inlet formed at a position in the middle of the solution (See Fig. 2 which shows membrane 42, raw liquid inlet where circulation channel 44 enters 40, raw liquid outlet where circulation channel 44 leavs 40, circulation channel 44, pump 36, inlet for an object solution for separation 32, and diluent solution inlet 38)

Regarding claim 14 DiLeo et al. discloses a method of preparing a solution having a changed composition of biological components with a module containing a separation membrane disposed therein by introducing a biological components-containing solution in the raw liquid side of the separation membrane, circulating the solution in the raw liquid side through a solution formed in the outside of the module, and taking out the solution passed through the separation membrane as the solution having a changed composition of biological components; wherein a diluting solution for the biological components-containing solution is additionally introduced into the raw liquid side of the separation membrane disposed in the module immediately after

introduction of the biological components-containing solution. (See Col. 1 Lines 5-20, Col. 4 Lines 9-34, and Fig. 2)

Regarding claim 19 DiLeo et al. discloses all the claim limitations as set forth above as well as the method of preparing a solution wherein a physiological salt solution or a buffer solution is used as the diluting solution. (See Abstract and Col. 1 Lines 48-49 where saline is physiological salt solution is used as a diluting solution)

Regarding claim 20 DiLeo et al. discloses all the claim limitations as set forth above as well as the method wherein the biological components are substances derived from blood plasma or serums (See Abstract)

6. Claims 22-26, and 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al. (US 7,441,666)

Regarding claim 22 Kim et al. discloses a method of preparing a solution having a changed composition of biological components from a biological components-containing solution by subjecting the biological components-containing solution to treatment in at least two steps; wherein the two steps are selected from (1) a step of adsorbing a portion or all of proteins having a molecular weight equal to or higher than that of albumin; (2) a step of removing a portion or all of proteins having a molecular weight equal to or higher than that of albumin by fractionation with a molecular sieve;

and (3) a step of concentrating proteins. (See Col. 23 Lines 25-55 where steps (1),(2), and (3) are performed when passing a solution through a membrane module)33

Regarding claims 23-25 Kim et al. discloses all the claim limitations as set forth above as well as the method of preparing a solution wherein a material containing one or more substances selected from cellulose, cellulose acetate, polycarbonate, polysulfone, poly(methacrylic acid) ester, poly(acrylic acid) ester, polyamide, polyvinylidene fluoride, polyacrylonitrile, polyester, polyurethane, polystyrene, polyethylene, and polypropylene is used in the step (1), (2), and (3). (See Col. 6 Lines 55-65 and Col. 23 Lines 25-55 where a membrane comprising polyamide is used to perform steps (1),(2), and (3))

Regarding claim 26 Kim et al. discloses all the claim limitations as set forth above as well as the method of preparing a solution wherein a material fixing one or more substances selected from polyethylene imine, is used in the step (1) or the step (2). (See Col. 10 Lines 48-50 where a membrane to be used in steps (1),(2), and (3) comprises a hydrophilic polymer and Col. 13 Lines 30-45 where hydrophilic polymer contains polyethylene imine)

Regarding claim 28 Kim et al. discloses all the claim limitations as set forth above as well as the method of preparing a solution wherein the biological components-

containing solution contains a sample of human-derived components. (See Col. 4 Lines 14-25 where human serum is used)

Regarding claim 29 Kim et al. discloses an apparatus for preparing a solution having a changed composition from a biological components-containing solution, wherein the apparatus comprises at least two kinds of means joined by a flow path and selected from (1) means of adsorbing a portion or all of proteins having a molecular weight equal to or higher than that of albumin; (2) means of removing a portion or all of proteins having a molecular weight equal to or higher than that of albumin by fractionation with a molecular sieve; and (3) means of concentrating proteins. (See Col. 23 Lines 25-55 where steps (1),(2), and (3) are performed when passing a solution through a membrane module and when passing through a membrane it is inherent that the means are joined by a flow path through the membrane)

Claim Rejections -35 USC § 102 or 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-3 and 6-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kim et al. (US 7,441,666)

Regarding claims 1-3 Kim discloses a method of preparing a solution having a composition of biological components changed to control the concentration ratio of albumin in the total proteins to be less than 0.3 by supplying a biological components-containing solution to a separation membrane having a 50 or higher comparative permeation ratio of at least Beta 2-microgloblin to albumin and passing the solution through the separation membrane. (See Abstract, Col. 4 Lines 14-25, Col. 23 Lines25-55, and Table 1) Kim et al. discloses a membrane designed to separate albumin and other high molecular weight components from low molecular weight components such as Beta 2-microgloblin and thus reducing concentration ratio of albumin to total protein in the resulting solution and appears to disclose the claimed properties, wherein the concentration ratio of albumin to total protein in the resulting solution is less than 0.3, or less than 0.1 and a membrane having a 50 or higher or a 70 or higher comparative permeation ratio of at least Beta 2-microgloblin to albumin, based on the results shown in Table 1.

Assuming even if the method of Kim does not specifically disclose the recited properties as the amount and type of components separated, the purity of the filtrate, and throughput time are variables that can be modified, among others, by adjusting

membrane properties or type of membrane, the precise ratio of albumin in the total proteins and comparative permeation ratio would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed ratio of albumin in the total proteins and comparative permeation ratio cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the membrane properties of Kim et al. to obtain the desired balance between the product purity and throughput time (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223).

Regarding claim 6 Kim discloses all the claim limitations as set forth above as well as the method of preparing a solution wherein the flow parts in the inside of the separation membrane have an asymmetric structure. (See Col. 4 Lines 14-16)

Regarding claim 7 Kim discloses all the claim limitations as set forth above as well as t method of preparing a solution wherein the biological components are a solution containing proteins extracted from substances derived from blood plasma, or serums (See Col. 4 Lines 14-25, and Col. 23 Lines 25-55)

Regarding claim 8 Kim discloses all the claim limitations as set forth above as well as a solution for proteome analysis obtained by a preparation method according to claim 1. It is inherent that when the method of claim 1 is carried out the result will produce a solution fully capable of being used for proteome analysis.

Regarding claim 9 Kim discloses all the claim limitations as set forth above as well as an analysis method of proteins contained in biological components by preparing a solution having a changed composition of the biological components by a method according claim 1 and then analyzing the proteins contained in the solution. (See Col. 23 Lines 25-55 where a solution is produced using the method of claim 1 and then analyzed.)

Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (US 7,441,666).

Regarding claims 4 and 5 Kim discloses all the claim limitations as set forth above but does not specifically disclose method of preparing a solution according to the claim 1, wherein the composition ratio of Beta 2-microgloblin in the total proteins in the solution having a changed composition of biological components is at least 10 times as high as the composition ratio of Beta 2-microgloblin in the total proteins in the biological components-containing solution and wherein the ratio is at least 100 times as high

While Kim does not specifically disclose the recited properties as the amount and type of components separated, the purity of the filtrate, and throughput time are

variables that can be modified, among others, by adjusting ratio of Beta 2-microgloblin in the starting and final solutions, the precise ratio of Beta 2-microgloblin in the starting and final solutions would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed change in ratio of Beta 2-microgloblin in the starting and final solutions cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the ratio of Beta 2-microgloblin in the starting and final solutions of Kim et al. to obtain the desired balance between the product purity and throughput time (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223).

Claim Rejections - 35 USC § 103

10. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over van Reis. (US 6,054,051)

Regarding claim 11 van Reis discloses an apparatus for preparing a solution for proteome analysis having a changed composition of biological components, wherein the apparatus is an apparatus having a module containing a separation membrane and passing the solution through the separation membrane and the module has a raw liquid inlet for the biological components-containing solution in the raw liquid side of the

separation membrane and an outlet of the filtrate passed through the separation membrane. (See Fig._1 where there is a membrane 30, inlet 16, and outlet 28)

While van Reis does not specifically disclose the separation membrane having a 50 or higher comparative permeation ratio of Beta 2- microgloblin to albumin it would have been obvious to one of ordinary skill in the art at the time of invention to change the comparative permeation ratio of Beta 2- microgloblin to albumin of the membrane in the apparatus of van Reis, because as the amount and type of components separated, the purity of the filtrate, and throughput time are variables that can be modified, among others, by adjusting a membranes comparative permeation ratio, the comparative permeation ratio would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed comparative permeation ratio cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the comparative permeation ratio of the membrane in van Reis to obtain the desired balance between the product purity and throughput time (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223).

Furthermore van Reis discloses that the specific membrane used in the device depends upon the specific application (See Col. 3 Lines 25-31 and Col. 5 Lines 10-15) and as such one of ordinary skill in the art at the time of invention would have been

motivated to choose a membrane having a 50 or higher comparative permeation ratio of Beta 2- microgloblin to albumin to obtain a desired end product in a specific application.

11. Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiLeo et al. (US 4,728,430)

Regarding claims 15-18 while DiLeo et al. does not specifically disclose the method wherein separation is carried out under the condition satisfying $0<Q2/Q1<1$, $0.005<Q2/Q1<0.5$, $0.5<Q2/Q3<1.5$, or $Q2/Q3$ is about 1 it would have been obvious to one of ordinary skill in the art at the time of invention to change the flow rates of raw liquid, the solution passed through the separation membrane, and the biological components-containing solution introduced into the raw liquid side and the diluting solution, the in the method of DiLeo et al., because as the amount of components separated, the purity of the filtrate, and throughput time are variables that can be modified, among others, by adjusting flow rate ratios on or through a membrane, the claimed flow rate ratios would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed comparative permeation ratio cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the flow rate ratios of the method of DiLeo et al. to obtain the desired balance between the product purity and throughput time (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it

has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223).

12. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (US 7,441,666)

Regarding claim 30 Kim et al. discloses all the claim limitations as set forth above as well as the use of liquid chromatography to analyze a product of filtration (See Col. 21 Lines 36-50) and it is inherent that the apparatus of Kim has a flow out channel and the liquid chromatography column has an inlet channel. Kim does specifically disclose the apparatus for preparing a solution comprising a liquid flow-out path to be joined to a liquid chromatograph.

While Kim et al. is silent as to the exact means by which the product of filtration is conveyed to a liquid chromatography column it would have been obvious to one of ordinary skill in the art at the time of invention provide a liquid flow-out path to be joined to a liquid chromatograph in the apparatus of Kim because doing so would allow one to quickly convey the product of filtration in the liquid chromatography column.

Furthermore connecting the output of one device to the input of another device when a product is meant to be conveyed from said one to another is well known in the art and one of ordinary skill in the art at the time of invention would have been motivated

to connect the devices in such a way so as to reduce product handling and to increase the speed at which the desired process can be performed in the devices.

Further still it is noted that one of ordinary skill in the art at the time the invention was made would have been led by the applied reference to forgo use of separate modules, along with their function and benefit, where doing so is technically feasible and would reduce cost. See In re Thompson, 545 F.2d 1290, 1229, 188 USPQ 365, 367 (CCPA 1976).

13. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (US 7,441,666)as applied to claims 1-9, 22-26, 28-29, and 30 above, and further in view of Ohno et al. (US 4,347,138)

Regarding claim 10 Kim discloses all the claim limitations as set forth above but does not disclose the analysis method of proteins wherein means of analyzing proteins is at least one selected from mass spectrometry, electrophoretic analysis, and liquid chromatography. Kim also teaches the use of liquid chromatography to analyze a product of filtration (See Col. 21 Lines 36-50) but does not specifically mention liquid chromatography performed on proteins contained in biological solutions.

Ohno et al. discloses the use of liquid chromatography to analyze proteins in solution having biological components which are separated by using a membrane. (See Example 1 where liquid chromatography is used to analyze samples)

It would have been obvious to one of ordinary skill in the art at the time of invention perform liquid chromatography in the method of Kim et al. because doing so is a known and accurate method for analyzing proteins which are products of filtration (See Ohno Example 1) and is known to be used as an analysis method for measuring products resulting from the method of Kim as described above. (See Kim Col. 21 Lines 36-50)

14. Claims 13 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiLeo et al. (US 4,728,430) as applied to claim12,14-20 above, and further in view of Kawai et al. (US 4,350,594)

Regarding claim 13 DiLeo discloses all the claim limitations as set forth above as well but does not disclose an apparatus for preparing a solution having a changed composition of biological components, wherein the apparatus comprises at least two liquid flow channels and the outlet of the object solution for separation of one liquid flow channel is joined directly or indirectly to an inlet for the object solution for separation of the other liquid flow channel.

Kawai et al. discloses the apparatus comprises at least two liquid flow channels and the outlet of the object solution for separation of one liquid flow channel is joined directly or indirectly to an inlet for the object solution for separation of the other liquid

flow channel. (See Fig. 1 where line 9 connects outlet of the flow channel 4 directly into the inlet of a second flow channel 10)

It would have been obvious to one of ordinary skill in the art at the time of invention to connect the outlet of one flow channel to the inlet of another as described by Kawai in the apparatus of DiLeo because doing so allows for the effective separation of a multitude of different blood components. (See Kawai abstract and Col. 2 Lines 33-43)

Furthermore one of ordinary skill in the art at the time of invention would have recognized that by connecting two flow channels each of which contains a membrane for filtering a solution the final product would be more pure than if only one flow channel was used. As such one of ordinary skill in the art would have been motivated to connect more than one flow channel together in order to obtain as pure a product as possible.

Regarding claim 21 DiLeo discloses all the calim limitations as set forth above but does not disclose the method of preparing a solution having a changed composition of biological components wherein two modules are employed and a solution obtained by the method according to the claim 14 is used in a first module and the method according to the claim 14 is carried out by the second module. (See Fig. 1 where line 9 connects outlet of the first module 4 directly into the inlet of a second module 10 and Col 1 line 65 – Col. 2 Line 8 where the method is separation of a component of blood)

Kawai et al. discloses a method wherein two modules are employed and a solution obtained by a method is used in a first module and the same method is carried out by the second module. (See Fig. 1 where line 9 connects outlet of the flow channel 4 directly into the inlet of a second flow channel 10 and)

It would have been obvious to one of ordinary skill in the art at the time of invention to employ two modules where a solution obtained by a method is used in a first module and the same method is carried out by the second module as described by Kawai in the method of DiLeo because doing so allows for the effective separation of a multitude of different blood components. (See Kawai abstract and Col. 2 Lines 34-43)

Furthermore one of ordinary skill in the art at the time of invention would have recognized that by connecting two modules containing a membrane for filtering a solution, and carrying out the same separation procedure in both, the final product would be more pure than if only one module was used. As such one of ordinary skill in the art would have been motivated to connect two modules containing a membrane for filtering a solution, and carrying out the same separation procedure in both, in order to obtain as pure a product as possible.

15. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (US 7,441,666) as applied to claims 1-10, 22-26, and 28-30 above, and further in view of Comper (US 2002/0022236).

Regarding claim 27 Kim et al discloses all the claim limitations as set forth above as well as the method of preparing a solution according to the claim 22, wherein a dye is added to an aqueous solution in the step (1) or the step (2) in order to dye albumin. (See Col. 23 Lines 25-55 where albumin coloring agent is used) Kim does not specifically disclose the use of a blue dye.

Comper discloses the use of a blue dye in order to detect albumin in a solution during a filtration process. (See [0085])

It would have been obvious to one of ordinary skill in the art at the time of the invention to add a blue dye as described by Comper to the solution of Kim because the dye of Comper because the blue dye is able bind to albumin selectively over other unwanted compounds during detection (See Comper [0085]) and it fulfills the need for a selective albumin coloring agent allowing for the detection of albumin in the solution as required by Kim. (See Col. 23 Lines 25-55)

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN M. HURST whose telephone number is (571)270-7065. The examiner can normally be reached on Mon. - Thurs. 6:30-5:00; Every Fri. off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. H./
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797